

Message Text

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PAGE 01 STATE 137417
ORIGIN HEW-06

INFO OCT-01 EA-12 ISO-00 OES-07 EUR-12 ARA-14 NEA-11
MED-03 SIG-03 /069 R

66011
DRAFTED BY DHEW/FDA:JRWEINROTH, M.D.:CM
APPROVED BY OES/ENP/EN:WJWALSHI III
DHEW/PHS/OASH/OIH:RFISCHER
EUR/NE:SWORREL(INFO)
EA/ANP:TWAJDA(INFO)
ARA/ECA:NBOUTON(INFO)
EA/J:EFEATHERSTONE(INFO)
NEA/EGY:KHONAN(INFO)
EUR/CAN:JROUSE,JR(INFO)

-----031768 010330Z /12

P 311830Z MAY 78
FM SECSTATE WASHDC
TO AMEMBASSY LONDON PRIORITY
AMEMBASSY CANBERRA PRIORITY
AMCONSUL SAO PAULO PRIORITY
AMEMBASSY TOKYO PRIORITY
AMEMBASSY CAIRO PRIORITY
AMEMBASSY OTTAWA PRIORITY
INFO AMEMBASSY BRASILIA PRIORITY

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E.O. 11652: N/A

TAGS: OGEN, ETR,D EIND, UK, BR, EG, JA

SUBJECT: FDA ADVISORY - INACCURATE READINGS WHEN USING
PH/BLOOD GAS SYSTEM (RECALL T 075-8)

1. FDA ADVISES OF THE FOLLOWING:

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A. PRODUCT INVOLVED: CORNING MEDICAL MODEL 175 PH/BLOOD
GAS SYSTEM

B. PRODUCT IDENTIFICATION - THE CORNING MEDICAL MODEL 175
PH/BLOOD GAS SYSTEM IS MANUFACTURED AND DISTRIBUTED BY
CORNING MEDICAL, A DIVISION OF CORNING GLASSWORKS,
MEDFIELD, MA 02052. THE INSTRUMENT MEASURES PH, PCO 2

AND PO 2 OF BLOOD AND CALCULATES BICARBONATE, BASE EXCESS, OXYGEN SATURATION AND OXYGEN CONTENT OF THE SAMPLE. ALL SERIAL NUMBERS ARE INVOLVED.

C. MANUFACTURING/RECALLING FIRM - CORNING MEDICAL, DIVISION OF CORNING GLASSWORKS, INDUSTRIAL PARK, NORTH STREET, MEDFIELD, MA 02052

2. REASON FOR RECALL: THE CORNING MEDICAL MODEL 175 PH/BLOOD GAS SYSTEM DIRECTLY MEASURES BLOOD PH, PCO 2 AND PO2 USING DEFINED ELECTRODE SYSTEMS. FROM THESE DIRECT MEASUREMENTS, THE INSTRUMENT CALCULATES THE NON-MEASUREABLE PARAMETERS; BICARBONATE, BASE EXCESS, OXYGEN CONTENT, AND OXYGEN SATURATION. THE EQUATIONS USED IN THESE CALCULATIONS ARE DESCRIBED IN THE SCIENTIFIC LITERATURE. THIS INSTRUMENT IS NORMALLY USED TO GENERATE VALUES AT THE MEASURING TEMPERATURE OF 37.0 DEGREES C. THE INSTRUMENT HAS THE ADDED FEATURE OF ENTERING ACTUAL PATIENT TEMPERATURE AND GENERATING VALUES OF PH AND BLOOD GASES CORRECTED FOR THE ENTERED TEMPERATURE. AN EXAMPLE OF A SITUATION IN WHICH THIS WOULD BE DESIREABLE IS OPEN HEART SURGERY DURING WHICH PATIENTS ARE HYPOTHERMIC. THE LITERATURE DESCRIBES THE FORMULAS USED TO CORRECT THE MEASURED PARAMETERS (PH, PCO 2 AND PO 2) FOR PATIENT TEMPERATURE. HOWEVER, THE SCIENTIFIC COMMUNITY HAS QUESTIONED THE VALIDITY OF GENERATING VALUES FOR THE UNCLASSIFIED

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NONMEASUREABLE PARAMETERS (BICARBONATE, BASE EXCESS, OXYGEN CONTENT AND OXYGEN SATURATION) FROM THE TEMPERATURE CORRECTED VALUES OF PH, PCO 2 AND PO 2. THE FIRM HAS CONTACTED AT LEAST TWO MEMBERS OF THE SCIENTIFIC COMMUNITY CONSIDERED TO BE THE MOST KNOWLEDGEABLE IN BLOOD GAS STUDIES. THEIR OPINION WAS THAT TEMPERATURE CORRECTION FOR THE NONMEASUREABLE PARAMETERS IS INAPPROPRIATE. BECAUSE OF THESE OPINIONS, THE FIRM HAS DECIDED TO DELETE THIS FEATURE OF TEMPERATURE CORRECTION FOR NONMEASUREABLE PARAMETERS FROM THE INSTRUMENT. THERE HAVE BEEN NO INJURIES OR DEATHS CONNECTED WITH THIS PROBLEM.

3. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE IF THEY HAVE RECEIVED "RECALL" INFORMATION CONCERNING THIS MEDICAL DEVICE AND FIELD MODIFICATION PROCEDURES. ANY QUESTIONS CONSIGNEES MAY HAVE SHOULD BE SENT FIRM ATTN: MR. DENNIS CARLSON.

4. CONSIGNEES AS FOLLOWS:

CORNING MEDICAL TOSCOPTY LIMITED
DIVISION OF CORNING LIMITED P. O. BOX 245

CHURCH LANE, HAWTHORNE 3122
ESSEX, ENGLAND VICTORIA, AUSTRALIA

MINISTRY OF HEALTH CELM CIAXA
CAIRO, EGYPT POSTAL 4022
-- SAO PAULO, 10307
-- SP BRAZIL

CORNING INTERNATIONAL SERVICES
KOWA BLDG 16 - ANNEX 9-20
AKASAKA 1-CHOME
MINATO-KU TOKYO
JAPAN

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FISHER SCIENTIFIC
111 SCOTIA COURT
WHITBY, ONTARIO

FISHER SCIENTIFIC COMPANY, LIMITED
196 WEST THIRD AVENUE
VANCOUVER, B.C.

FISHER SCIENTIFIC COMPANY, LIMITED
P. O. BOX 1020
8505 DEVONSHIRE ROAD
TOWN OF MOUNT ROYAL
MONTREAL, QUEBEC H3C2X3. CHRISTOPHER

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NNN

Message Attributes

Automatic Decaptoning: X
Capture Date: 01 jan 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, RECALLS
Control Number: n/a
Copy: SINGLE
Draft Date: 31 may 1978
Decaption Date: 01 jan 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 jan 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1978STATE137417
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:CM
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D780228-0685
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1978/newtext/t1978052/aaaaabis.tel
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Litigation Codes:
Litigation History:
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Message ID: dcfbfa96-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
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Original Previous Classification: n/a
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Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: N/A
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 2571659
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY - INACCURATE READINGS WHEN USING PH/BLOOD GAS SYSTEM (RECALL T 075-8)
TAGS: OGEN, ETRD, EIND, UK, BR, EG, JA, FDA
To: LONDON CANBERRA MULTIPLE
Type: TE
vdkvgwkey: odbc://SAS/SAS.dbo.SAS_Docs/dcfbfa96-c288-dd11-92da-001cc4696bcc
Review Markings:
Sheryl P. Walter
Declassified/Released
US Department of State
EO Systematic Review
20 Mar 2014
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